Clinical Policy: Factor VIIa, Recombinant (NovoSeven RT)

Reference Number: CP.PHAR.220
Effective Date: 05.01.16
Last Review Date: 02.18
Line of Business: Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Recombinant factor VIIa (NovoSeven® RT) is a vitamin K-dependent glycoprotein that promotes hemostasis by activating the extrinsic pathway of the coagulation cascade.

FDA Approved Indication(s)

NovoSeven RT is a recombinant factor VIIa concentrate/intravenous injection indicated for:

- Treatment of bleeding episodes and perioperative management in adults and children with hemophilia A or B with inhibitors, congenital FVII deficiency, and Glanzmann's thrombasthenia with refractoriness to platelet transfusions, with or without antibodies to platelets;
- Treatment of bleeding episodes and perioperative management in adults with acquired hemophilia.

Policy/Criteria

Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that NovoSeven RT is a **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Congenital Hemophilia A or B with Inhibitors (must meet all):

1. Diagnosis of congenital hemophilia A (factor VIII deficiency) or B (factor IX deficiency) with inhibitors (factor VIII or IX antibodies);
2. Prescribed by or in consultation with a hematologist;
3. Request is for one of the following:
   a. Control and prevention of bleeding episodes;
   b. Perioperative management;
4. Dose does not exceed 90 mcg/kg every two hours.

Approval duration: 3 months

B. Congenital Factor VII Deficiency (must meet all):

1. Diagnosis of congenital factor VII deficiency;
2. Prescribed by or in consultation with a hematologist;
3. Request is for one of the following:
   a. Control and prevention of bleeding episodes;

b. Perioperative management;
4. Dose does not exceed 30 mcg/kg every four hours.

Approval duration: 3 months

C. Glanzmann's Thrombasthenia (must meet all):
1. Diagnosis of Glanzmann's thrombasthenia;
2. Prescribed by or in consultation with a hematologist;
3. Condition is refractory to platelet transfusions;
4. Request is for one of the following:
   a. Control and prevention of bleeding episodes;
   b. Perioperative management;
5. Dose does not exceed 90 mcg/kg every two hours.

Approval duration: 3 months

D. Acquired Hemophilia (must meet all):
1. Prescribed by or in consultation with a hematologist;
2. Diagnosis of acquired hemophilia as evidenced by the presence of coagulation factor VIII inhibitors (autoantibodies);
3. Request is for one of the following:
   a. Control and prevention of bleeding episodes;
   b. Perioperative management;
4. Dose does not exceed 90 mcg/kg every two hours.

Approval duration: 3 months

E. Other diagnoses/indications
1. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**
1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 90 mcg/kg every two hours (30 mcg/kg every four hours for congenital factor VII deficiency).

Approval duration: 3 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 3 months (whichever is less); or
2. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
Not applicable

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Treatment of bleeding episodes	Congenital hemophilia A or B with inhibitors: • 90 mcg/kg IV every 2 hours, adjustable based on severity of bleeding until hemostasis is achieved • 90 mcg/kg IV every 3-6 hours after hemostasis is achieved for severe bleeds Congenital factor VII deficiency: 15-30 mcg/kg IV every 4-6 hours until hemostasis is achieved Glanzmann's thrombasthenia: 90 mcg/kg IV every 2-6 hours until hemostasis is achieved Acquired hemophilia: 70-90 mcg/kg IV every 2-3 hours until hemostasis is achieved	Congenital factor VII deficiency: 30 mcg/kg every 4 hours All other indications: 90 mcg/kg every 2 hours
Peri-operative management	Congenital hemophilia A or B with inhibitors: *Minor surgery:* • 90 mcg/kg IV immediately before surgery, repeat every 2 hours during surgery • 90 mcg/kg IV every 2 hours after surgery for 48 hours, then every 2-6 hours until healing has occurred *Major surgery:* • 90 mcg/kg IV immediately before surgery, repeat every 2 hours during surgery • 90 mcg/kg IV every 2 hours after surgery for 5 days, then every 4 hours until healing has occurred	Congenital factor VII deficiency: 30 mcg/kg every 4 hours All other indications: 90 mcg/kg every 2 hours

Indication	Dosing Regimen	Maximum Dose
	Congenital factor VII deficiency: 15-30 mcg/kg IV immediately before surgery and every 4-6 hours for the duration of surgery and until hemostasis is achieved Glanzmann's thrombasthenia: • 90 mcg/kg IV immediately before surgery and repeat every 2 hours for the duration of the procedure • 90 mcg/kg IV every 2-6 hours to prevent postoperative bleeding Acquired hemophilia: 70-90 mcg/kg immediately before surgery and every 2-3 hours for the duration of surgery and until hemostasis is achieved	

VI. Product Availability

Vial: 1, 2, 5, 8 mg

VII. References

1. NovoSeven RT Prescribing Information. Plainsboro, NJ: Novo Nordisk, Inc.; October 2017. Available at http://www.novo-pi.com/novosevenrt.pdf. Accessed November 29, 2017.
2. Srivastava A, Brewer AK, Mauser-Bunschoten EP, et al. Guidelines for the management of hemophilia. Haemophilia. Jan 2013; 19(1): e1-47.
3. Medical and Scientific Advisory Council (MASAC) of the National Hemophilia Foundation (NHF): Database of treatment guidelines. Available at https://www.hemophilia.org/Researchers-Healthcare-Providers/Medical-and-Scientific-Advisory-Council-MASAC/MASAC-Recommendations Accessed November 29, 2017.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J7189	Factor VIIa (antihemophilic factor, recombinant), per 1 mcg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy split from CP.PHAR.12.Blood Factors and converted to new template. Removed specific titer levels and factor VIII dose increases. Approval period for non-prophylactic use is edited to provide 3 months on initial approval and one 3-month re-auth. Added criteria for Glanzmann's thrombasthenia. Reviewed by specialist.	04.01.16	05.16
Safety information removed. Wording for uses and approval periods for all blood factor products made consistent across all policies. Efficacy statement added to renewal criteria. Hemophilias are specified as "congenital" versus "acquired" across blood factor policies where indicated. Added requirement that acquired hemophilia be evidenced by the presence of factor VIII inhibitors. Reviewed by specialist-hematology/internal medicine.	04.01.17	05.17
1Q18 annual review: - No significant changes - Converted to new template - References reviewed and updated.	11.29.17	02.18

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.